

What is claimed is:

1. A method of determining the presence of a substance in a sample, comprising the steps of: (a) providing a sample; (b) measuring the amount of the substance in the sample; (c) comparing the amount of the substance in the sample to a predetermined threshold; and (d) determining the presence of the substance in the sample based on the comparison.

1. A method of delivering a therapeutic gene product to the bloodstream of a subject, the method comprising:
administering a construct comprising a nucleic acid molecule encoding a protein and a eukaryotic promoting sequence operably linked thereto into the
5 gastrointestinal tract of a mammalian patient in a manner resulting in the genetic transformation of intestinal cells with the construct so that the sequence expresses a protein so that the patient is in need of and the protein is secreted from the cells;
and
allowing the genetically transformed cell to express the protein in a
10 therapeutically effective amount thereby treating the patient.
2. The method of claim 3, wherein the intestinal cell is an absorptive cell of the small intestine.
3. The method of claim 1, wherein the intestinal cell is a columnar epithelial cell of the large intestine.
- 15 4. The method of claim 1, wherein the protein is secreted into the bloodstream.
5. The method of claim 1, wherein the protein is secreted into the gastrointestinal tract.
6. The method of claim 1, wherein the nucleic acid is administered as
20 naked nucleic acid.
7. The method of claim 1, wherein said administering is by oral administration.

8. The method of claim 1, wherein expression of the therapeutic protein in the mammalian patient is for a period of about two to three days.

9. A method of transforming an intestinal epithelial cell *in vivo*, the method comprising:

5 introducing into the gastrointestinal tract of a mammalian subject a construct comprising a nucleic acid molecule encoding a protein and a eukaryotic promoting sequence operably linked thereto, said introducing resulting in genetic alteration cells of the intestine that the sequence expresses a protein that the patient is in need of and the protein is secreted from the cells.

10 10. The method of claim 9, wherein the protein is secreted into the bloodstream.

11. A system for delivery of a therapeutic gene product comprising:
a construct comprising a nucleic acid molecule encoding a therapeutic gene product and a eukaryotic promoting sequence operably linked thereto; and
15 means for introducing the construct into the gastrointestinal tract of a mammalian subject in a manner resulting in the genetic transformation of cells of the intestine with the construct;
wherein introduction of the construct into the gastrointestinal tract results in transformation of intestinal epithelial cells with the nucleic acid, expression and
20 delivery of the encoded therapeutic gene product.

12. The system of claim 11, wherein the gene product is a protein and the protein is secreted into the gastrointestinal tract or the bloodstream of the mammalian subject.

13. The system of claim 11, wherein the cells transformed are absorptive cells of the small intestine or columnar epithelial cells of the large intestine.

14. A pharmaceutical composition suitable for administration into the
5 gastrointestinal tract of a mammalian patient, the composition comprising a DNA construct encoding a DNA or interest, which construct is suitable for expression of a therapeutic protein in an intestinal cell of a mammalian patient.

15. The pharmaceutical composition of claim 14, wherein the formulation is substantially free of lipofectin, dendrimers, and viral components.

10 16. The pharmaceutical composition of claim 14, wherein the composition is formulated for oral administration.

17. The pharmaceutical composition of claim 14, wherein the composition is formulated for direct insertion in the gastrointestinal tract through the rectum.